U. S. DEPARTMENT OF AGRICULTURE
Agricultural Marketing Service
Dairy Programs
Dairy Grading Branch

Instructions for

CERTIFICATION OF DAIRY PRODUCTS INTENDED FOR EXPORT TO THE EUROPEAN UNION

The Following instructions and guidelines are excerpted from DA Instructions 918-I, Section R.

R.3.i.2.2 Special Considerations for Health Certificates to European Union Countries

These instructions establish the responsibilities and procedures to be used by the Dairy Grading Branch for providing official certification services and auditing Applicants for compliance for manufactured, processed and related dairy products exported to the European Union (EU). The EU somatic cell and standard plate counts for dairy products differ from those required by the United States. The program outlined in these instructions shall be used to certify compliance with the *Council Directive 92/46/EEC* allowing export of dairy products from the United States to the EU.

At the time of this issuance, the following 25 countries are members of the European Union:

Austria	Germany	The Netherlands	Belgium
Greece	Portugal	Denmark	Ireland
Spain	Finland	Italy	Sweden
France	Luxembourg	United Kingdom	Poland
Slovakia	Slovenia	Cyprus	Estonia
Czech Republic	Hungary	Latvia	Lithuania
Malta			

In addition, the following EU aligned countries are also eligible to receive EU certificates:

Norway	Iceland	Liechtenstein

R.3.i.2.2.1 Products Covered

The requirement to provide an EU certificate is controlled by the importing country or port authority within the EU. Generally, all dairy products which are readily recognized as a dairy product, or require in their standard of identity that they originate from milk will require an EU certificate. In addition, composite milk products which either utilize a dairy product as a characterizing effect or contain dairy ingredients as an essential part of the product generally will require certification if exported to the EU. Where uncertainty exists as to which composite milk products require certification for export to the EU, the Applicant should contact their importer to determine if a certificate is needed. All composite products containing cheese as an essential ingredient and intended for export to the EU require certification. Examples of dairy products and composite products <u>which require</u> certification are:

Milk	Cream	Butter	Cheese
Yogurt	Buttermilk	Kefir	Caseins
Butter Oil	Lactoserum	Dairy Fat Material	Ice Cream
Partially Dehydrated Milks		Totally Dehydrated Milks	

Examples of composite products identified as containing only a minimum part of milk or milk product and which generally do not require certification under 92/46/EEC are:

Milk chocolate	Butter Crackers	Cookies	Creamed Spinach
Whiskey Cream	Breton Crepes		

R.3.i.2.2.2 Effective Date

The effective date for establishing documentation of the somatic cell and bacteria records compliance system under this Instruction shall be April 21, 1997, for all dairy product(s)/ingredient(s) intended for export to the EU.

R.3.i.2.2.3 Dairy Plant Reference List

All domestic plants producing dairy or related products for export to the European Union must be identified on a list of plants (Dairy Plant Reference List) established by the Food and Drug Administration (FDA) . This list is maintained by the FDA and updated periodically. Plants wishing to request inclusion on this list can do so by contacting:

Food and Drug Administration
Regulations & Enforcement Branch (HFS-306)
Division of Programs and Enforcement Policy
Office of Plant and Dairy Foods and Beverages
Center for Food Safety and Applied Nutrition
5100 Paint Branch Pkwy
College Park, MD 20740
Tel: (301) 436-1492 Fax: (301) 436-2632

R.3.i.2.2.4 Council Directive 92/46/EEC Requirements

The requirements for dairy products imported into the EU are detailed in *Council Directive 92/46/EEC*. This comprehensive directive addresses many issues relative to milk production and processing. Countries outside of the EU that wish to provide dairy products to that market are required to provide certificates that indicate compliance with the requirements of *Council Directive 92/46/EEC* (92/46/EEC).

As a result of the negotiations that have taken place with the European Commission, we are confident that milk produced and dairy products manufactured under the United States system provide safeguards at least equivalent to the requirements of 92/46/EEC. There are, however, two quality-related differences in the two systems. The somatic cell and bacterial standard plate count requirements, as well as the method of calculating somatic cell and bacteria averages (geometric mean), differ from the system in place in the United States. In order to certify dairy product shipments to the European Union, the Dairy Grading Branch will require dairy product manufacturers to certify compliance with the somatic cell and bacterial standard plate count requirements of 92/46/EEC. The requirements are as follows:

- ★ The maximum somatic cell count in raw cows milk for the production of heat-treated milk, milk products, and other milk-based products is 400,000 somatic cells per ml.

- ★ The maximum bacterial standard plate count for raw cows milk for the production of heat-treated milk, milk products, and other milk-based products is 100,000 bacteria per ml.

R.3.i.2.2.5 Applicant's Responsibility

R.3.i.2.2.5.1

The Applicant shall apply for and obtain certification for product destined to the EU. It is the responsibility of the Applicant to ensure that they are included on the list established by the Food and Drug Administration. They are also responsible to have records demonstrating that dairy products and all applicable dairy ingredients which are intended for export to the EU are produced in plants which can demonstrate and attest to compliance with the EU Directive regarding somatic cell and bacteria counts for raw milk. Dairy plants that supply dairy product(s) or ingredient(s) to an Applicant but which do not ship dairy product directly to the EU would not be required to be on the Dairy Plant Reference list, but may be subject to Dairy Grading Branch audits.

R.3.i.2.2.5.1.1

Applicants which utilize imported dairy products and ingredients intended to be used for the production of products which will be shipped to the EU must present an EU Annex B certificate issued by the regulatory agency of the country of origin certifying that these imported dairy products and ingredients meet Council Directive 92/46 regarding somatic cell and bacteria counts for raw milk.

R.3.i.2.2.5.2

The primary purpose of the EU export certificate is to certify that the products were manufactured under a system that is equivalent to the requirements of the EU Directives. Since differences exist in somatic cell and bacterial standards, the EU export certificate also must certify that the raw milk used in the production of products exported to the EU meets the requirements of the EU Council Directive 92/46/EEC. This certification is necessary for all dairy products and dairy ingredients that may be included in a product requiring an EU certificate issued by the Dairy Programs. It is the responsibility of the individual or firm requesting an export certificate to assemble and maintain the necessary production records and Certificates of Conformance for the products covered by each certificate. This policy and procedure was cooperatively developed and agreed upon by industry and trade association representatives who participated in an April 1997, Joint USDA/FDA/Industry Task Committee meeting.

The Dairy Grading Branch provides certificates based upon information provided by the applicant. This information includes a Certificate of Conformance that the products listed on the certificate comply with the EU Directive. Through the Dairy Programs audit program, we are able to assess the accuracy of the documentation provided by the applicant. (See Exhibit R.10.h).

The Applicant shall submit the following information to the Dairy Grading Branch to begin the process of issuance of certificates:

- ★ Certificate of Conformance on company letterhead signed by a responsible official for the applicant (see Exhibit R.10.i)

- ★ All product information requested on the Instructions For Completion of Health Certificate Worksheet For Export Certificates To The European Union. (see Exhibit R.10.h)

- ★ Each request for an EU export certificate shall include production lot identification codes and production dates for the products covered by the certificate. This information is necessary to facilitate the tracking of the products certified during the audit procedures.

- ★ Attestations or certificates from domestic and foreign suppliers of dairy products and ingredients, when required by USDA.

R.3.i.2.2.5.2.1

If production lot identification codes and production dates are not included in the request, issuance of certificates will be denied until the information is provided.

Failure to maintain adequate records and complete files of Certificates of Conformance, to substantiate each request for a certificate as determined during an audit, will result in immediate ineligibility to receive EU export certificates. In order to resume the ability to receive future certificates, an audit of the exporter or firm will be conducted by the Dairy Programs to determine if adequate documents and records are maintained prior to issuance of the future certificate. This process will delay issuance of the EU export certificate.

Applicants are advised that production codes on product containers and shipping container seal numbers documented on the certificate are required by some importing countries or port authorities.

R.3.i.2.2.5.2.2

The exporter or firm requesting a certificate is solely responsible for assembling and maintaining all production records and Certificates of Conformance for the dairy products and dairy ingredients used. The Certificates of Conformance shall provide an accurate record trail leading to the raw milk used for the dairy components requiring EU certification.

R.3.i.2.2.5.2.3

Certification fee shall be at the currently published rate for one hour.

R.3.i.2.2.5.3

Grade A cows milk and Grade B cows milk in the U.S. is regulated at a somatic cells count of 750,000 per ml. Grade A milk in the U.S. is already regulated at a bacterial standard plate count of 100,000 or less. The recommended regulatory bacterial level for Grade B cows milk in the U.S. is 500,000 per ml. Testing of the milk supply will be necessary to document compliance (both grades of milk for somatic cell count and Grade B milk for bacterial counts) with these requirements for shipment of dairy products to the EU.

While a number of different compliance systems devised by the Applicant may result in compliance with this Instruction and the requirements of 92/46/EEC, the Dairy Grading Branch considers the following systems as minimal requirements. The Dairy Grading Branch will audit the system used by the Applicant to verify compliance with somatic cell and bacterial plate count requirements of 92/46/EEC.

R.3.i.2.2.5.3.1

The dairy plant shall have somatic cell and bacterial standard plate count records available to confirm that sufficient raw milk meeting the somatic cell and plate

count requirements are received at the facility manufacturing dairy products for shipment to the EU. The following examples would be considered minimally acceptable for a dairy plant receiving raw milk:

1. The dairy plant randomly samples 10% of the tankers providing milk to a processing plant on one randomly selected day each month for somatic cell count and on two randomly selected days each month for bacterial standard plate count, as necessary, or

2. The dairy plant analyzes each individual bulk tanker sample of raw milk for somatic cell and bacterial standard plate count, as necessary. All sample results for somatic cell count or bacterial standard plate count taken on the same day are averaged together (arithmetic average or geometric mean at the Applicant's option), producing one average value for the somatic cell count and one average value for bacteria count, or

3. Records are maintained that link the products exported to the EU with actual somatic cell count and bacterial counts to provide assurances on compliance to 92/46/EEC, or

4. Any other procedures which can be demonstrated to certify the conformance of the somatic cell and bacterial counts meet the EU requirements.

Through any of the above procedures, the dairy plant will be able to confirm that the geometric mean or arithmetic average for milk received during the:

- ★ prior two months and the current month (3 months total) for somatic cell counts, and

- ★ the prior month and the current month (2 months total) for bacteria counts, meets the requirements of 92/46/EEC.

R.3.i.2.2.5.3.2

The following example would be considered minimally acceptable for a plant or broker utilizing dairy products or ingredients, but not producing them when the final composite food is intended for export to the EU.

1. The plant has on file and available for audit attestation from their dairy supplier that the dairy product(s)/ingredient(s) meet 92/46/EEC for somatic cell and bacterial standard plate count requirements. The attestation should at a minimum include:

- ★ a clear statement that the dairy product(s)/ingredient(s) have been produced under a system that results in compliance with the somatic cell and bacterial requirements of 92/46/EEC,

- ★ the dates of production and processing of the raw milk,

- ★ documentation of where this compliance can be obtained,

- ★ a signature establishing the company and individual attesting to these statements,

- ★ a date when the attestation was signed.

2. If the dairy product/ingredient(s) is imported into the United States from another country, the product(s)/ingredient(s) must have a certificate issued by the sovereign government of the exporting country providing the same assurance as the certificate issued by the Dairy Grading Branch of AMS (see Exhibit E.1, “Health Certificate”). This includes products/ingredient(s) imported from the EU or countries maintaining equivalency agreements with the EU.

3. Records shall be maintained to link the products exported to the EU with attestations or certificates from the dairy product or ingredient supplier that provide assurances on compliance to 92/46/EEC equivalent to the Health Certificates provided by the Dairy Grading Branch.

R.3.i.2.2.5.4 Calculation of Geometric Mean (G.M.)

The European Union (EU) uses a geometric mean which is a calculated average to determine compliance with the somatic cell and bacterial standard plate count requirements of 92/46 EEC. For purposes of Dairy Grading Branch (AMS) certification, the values used for calculation of the geometric mean are obtained from the average value of bulk tanker samples (10%) taken once per month over a three-month period for somatic cell count and twice per month over a two-month period for bacteria counts.

R.3.i.2.2.5.4.1

Somatic Cell Count Example Calculations:

1. Determine the bulk tanker somatic cell count average for each of the prior two months and including the current month (3 months total).

2. Multiply each of the three monthly averages from 1 above together.

3. Compute the cube root of the result to obtain the geometric mean. (Note, many calculators have a key labeled "$X^{1/y}$" which can be used to calculate the geometric mean. "X" equals the result from 2 above and "y" equals 3.)

Somatic Cell Count Monthly Average	Geometric Mean
Month # 1 - 400,000	
Month # 2 - 350,000	
Month # 3 - 300,000	347,000 for Month #3
Month # 4 - 600,000	397,000 for Month #4
Month # 5 - 400,000	416,000 for Month #5
Month # 6 - 450,000	476,000 for Month #6

G.M. (somatic cell counts) = $\sqrt[3]{\text{Month\#1} \times \text{Month\#2} \times \text{Month\#3}}$

G.M.(for Month #3) = 347,000

R.3.i.2.2.5.4.2

Bacterial Standard Plate Count Example Calculations:

1. Determine the bulk tanker bacterial standard plate count average from 10% of the tankers received on two separate randomly selected days per month. Obtain two bacterial averages from the current month and two from the prior month for a total of four.

2. Multiply each of these four most recent counts from 1 above together.

3. Compute the fourth root of the result to obtain the geometric mean. (Note, many calculators have a key labeled "$X^{1/y}$" which can be used to calculate the geometric mean. "X" equals the result from 2 above and "y" equals 4.)

Bacterial Standard Plate Count Average Values	Geometric Mean
Month # 1 - Sampling #1 (Month 1-1) - 450,000	
Month # 1 - Sampling #2 (Month 1-2) - 250,000	
Month # 2 - Sampling #1 (Month 2-1) - 200,000	
Month # 2 - Sampling #2 (Month 2-2) - 150,000	241,028 for Month #2

Month # 3 - Sampling #1 (Month 3-1) - 700,000
Month # 3 - Sampling #2 (Month 3-2) - 500,000 320,109 for Month #3

G.M. (Bact.)= $\sqrt[4]{\text{Month1-1 x Month 1-2 x Month 2-1 x Month 2-2}}$

G.M.=241,028 for Month #2

R.3.i.2.2.5.5 Retention of Records

The plant shall retain documentation of all somatic cell and bacteria records or attestations for a minimum of 12 months after the date of shipment or since the last audit, whichever is longer, and provide these records to Dairy Grading Branch during any on-site records audit.

R.3.i.2.2.5.6 Minor Ingredients

Minor dairy ingredients making up a composite food may not require attestation or a certificate, however, this is under the control of the importing country. An example of a minor ingredient is starter culture used in cheesemaking when the starter comprises 3% or less of the milk.

R.3.i.2.2.6 Dairy Grading Branch Responsibility

R.3.i.2.2.6.1 Audits of the Compliance Systems

Audits of Compliance Systems for Somatic Cell and Bacterial Plate Count Records: The Dairy Grading Branch will audit the compliance system at each processing facility requesting certificate(s) for product shipment to the EU at least once per year, regardless of the frequency of shipment or amount of product shipped. The compliance system will be audited against the requirements 92/46/EEC and this Instruction.

See Section T for further guidance for conducting the audits for verifying the conditions for shipment to the EU.

R.3.i.2.2.6.2 Issuance of Certificates and Fees

Upon request, the Dairy Grading Branch will provide certificates to qualified Applicants. Dairy Grading Branch will provide these certificates within three to five business days of the receipt of a properly completed request. If requested by the Applicant, the certificates can be express-mail delivered at the Applicant's expense.

The Dairy Grading Branch will review and verify all information submitted by the Applicant. Upon verification of necessary information, the certificate shall be completed, signed, and forwarded to the Applicant.

R.3.i.2.2.6.3 Liaison With States

The Dairy Programs will continue to work closely with State regulatory agencies, NASDA, and the Milk Safety Branch of FDA to determine if State records could provide somatic cell and plate count certification for the dairy producers and processors in a particular State. If this 92/46/EEC compliance system can be developed, it may not be necessary for AMS to conduct audits of specific dairy plants in that particular State. (This is dependent upon the source of all raw milk processed by the Applicant originating from a state or states operating a compliance system which the Dairy Grading Branch has determined to meet the somatic cell and bacterial standard plate count requirements of 92/46/EEC.) The development of a State compliance system would not preclude individual plants from establishing their own compliance systems for somatic cell and bacteria counts to verify compliance with 92/46/EEC.

R.10 Exhibits

United States Department of Agriculture
Agricultural Marketing Service
Dairy Grading Branch
800 Roosevelt Rd
Building A, Suite 370
Glen Ellyn, IL 60137

INSTRUCTIONS FOR COMPLETION OF HEALTH CERTIFICATE WORKSHEET FOR EXPORT CERTIFICATE TO THE EUROPEAN UNION

Applicants for health certifications will be subjected to annual audits to verify compliance in accordance with DA Instruction 918-I, R.3.i.2.2.

- **Complete all the information on the attached worksheet on a single sheet.**
  - All information is required except "Code number" of product. The number of **packaging units** and **net weight** is for the entire shipment covered by the certificate. Show units of weight (e.g. Kg, lbs.)All the information shall be provided on a **single** sheet in the format provided. Worksheets not properly completed will **not be processed.** It is the exporter's responsibility to verify all documentation requirements for shipments intended for export to the EU.

- **Signature and date by the responsible official for the company is required on the worksheet.**

- **Provide a copy of the appropriate "Certificate of Conformance" with your request.**
  - Transfer the attached "Certificate of Conformance" to your company's letterhead paper and complete the appropriate certification section(s). Requests without a completed "Certificate of Conformance" will not be processed. Requests for multiple certificates in the same request require only one "Certificate of Conformance", provided the information is applicable to the entire request.

- **Certificates may be issued upon request in any of the European Union official languages**.
  - In order for the worksheet information to be provided in the requested language, the applicant shall provide the necessary wording in English and in the requested language.

- **Completed documents for requests will be returned to the applicant.**
  - If you require special handling of the completed certificate, such as special mailings or tracking, we request that you provide the required air bills. (Federal Express is the only express service that makes daily scheduled stops at our office. Packages for other services may not be picked up daily.)
- **Mail or fax the completed documents to:**

Export Processing
USDA, Agricultural Marketing Service
Dairy Division, Dairy Grading Branch,
Room 2746-S
1400 Independence Avenue, SW
Washington, D.C. 20250-0230

Fax Number: 202-720-2643
Phone Number: 202-720-7473

- **EU Health Certificates will be billed at the rate of one hour of the currently published hourly rate for each copy issued**.

Allow 5 days for processing

WORKSHEET FOR EUROPEAN UNION HEALTH CERTIFICATE

All information must be properly completed

Consignor (Name and Address in full)	Consignee (Name and Address in full)

Manufacturer of product being	Intended Destination of Product
Plant Name	EU Member State
EU Plant Number	Place of Destination
Place of Loading for Exportation	

Means of Transport & Consignment ID	
❒ Ship ❒ Air ❒ Rail ❒ Truck	Consignment Identification Details
Ship Name, Flight Number, Registration Info, Container number	

Identification of Product	
Code Number (as appropriate)	Number of Pkg Units
	Net Weight
Packaging	
Date of manufacture (For audit purposes, not shown on Certificate)	

I declare the above information is true and correct to the best of my knowledge:

_____ _____

Signature of agent for applicant Date

Return Address	Billing Information
Company	Company Name
Contact Name	Tax I.D. Number
Address	Billing Address
	Point of Contact
City, State	Phone Number
Telephone	Fax Number
❒ FedEx Contract	
❒ US Mail	

(This Certificate of Conformance must be provided with each request for sanitary certificates provided by the Dairy Grading Branch, Dairy Programs, Agricultural Marketing Service, United States Department of Agriculture, for shipment to the EU. **The Certificate of Conformance shall be provided on company letterhead that includes company name, address and phone number**. This Certificate of Conformance shall be signed and dated for each shipment of product; "blanket certificates" are not acceptable.)

Certificate of Conformance

Applicant European Union Certification:

I hereby certify that all of the dairy products and/or dairy ingredients used for the production of the products included in the attached request for certification were produced from raw milk meeting the somatic cell (400,000 per ml.) and bacterial standard plate count (100,000 per ml.) requirements of the European Commission Council Directive 92/46/EEC Annex A, Chapter IV.

The signer of this Certificate of Conformance acknowledges sole responsibility for maintaining adequate records to trace the production and Certificates of Conformance for all dairy products or ingredient use in the products presented for certification. Failure to maintain such records will cause ineligibility to receive certifications to the European Union.

_____ _____

(Signature and Title of Individual Providing Certification) **(Date)**

LOT NUMBERS AND MANUFACTURING DATES COVERED BY THIS CERTIFICATE OF CONFORMANCE ARE LISTED BELOW:

(This Certificate of Conformance must be obtained for supplier with each shipment of dairy ingredients used in product manufactured for shipment to the EU. **The Certificate of Conformance shall be provided on company letterhead that includes company name, address and phone number**. This Certificate of Conformance shall be signed and dated by the supplier for each shipment of product; "blanket certificates" are not acceptable. All lot number must be traceable to the production records of product certified by Dairy Grading Branch, Dairy Programs, Agricultural Marketing Service, United States Department of Agriculture for shipment to the EU.)

Certificate of Conformance

Dairy Ingredient Supplier:

I hereby certify that the dairy products included in the attached manifest were produced from raw milk meeting the somatic cell (400,000 per ml.) and bacterial standard plate count (100,000 per ml.) requirements of the European Commission Council Directive 92/46/EEC Annex A, Chapter IV.

_____ _____

(Signature and Title of Individual Providing Certification) (Date)

LOT NUMBERS AND MANUFACTURING DATES COVERED BY THIS CERTIFICATE OF CONFORMANCE ARE LISTED BELOW.